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December 2, 1997

Aerojet Site Team Members:

At our Aerojet Site Team meeting on October 3rd, we discussed the five perchlorate health consultations in which Dr. Underwood reviewed the perchlorate exposure to consumers of water from five water purveyors in the area near the Aerojet site. She has received comments from the site team members and is currently preparing responses which will be appended to the health consultations before they become final.

At the meeting Dr. Underwood also presented the idea of doing a follow-up health study focusing on newborn thyroid function. It was anticipated that the Environmental Health Investigations Branch (EHIB) staff from the California Department of Health Services (CDHS) would be working with staff from the Exposure Investigation Unit of the Agency for Toxic Substances and Disease Registry (ATSDR) to carry out the dose reconstruction part of the study. Unfortunately, ATSDR has had to focus on other sites and could not come to California to discuss the dose reconstruction until at least January, 1998. In the meantime, EHIB staff have been trying to identify local programs with the technical expertise to carry out the dose reconstruction project.

Enclosed you will find a copy of a health consultation written by CDHS staff describing the different types of health data which were reviewed in order to gain a better understanding of the effects of perchlorate exposure in the Rancho Cordova area. These include data from the Genetic Disease Branch of CDHS pertaining to neonatal hypothyroidism, hospital discharge data from the Office of Statewide Health Planning and Development (OSHPD) of CDHS pertaining to goiter, information on two blood disorders, and information from the California Cancer Registry for childhood leukemia.

We will be holding our next site team meeting on Thursday, December 11, 1997 at 1:00 p.m. at the Department of Toxic Substances Disease Control, Region 1, 10151 Croydon Way, Suite 3, Sacramento. Dr. Jeff Jacobs will join us to discuss the enclosed health consultation and the follow-up health study. We hope that you will be able to join us. If you have any questions about the meeting, please feel free to contact me at (510) 450-3818.

Sincerely,

Jane Riggan

Jane Riggan, M.S.W.
Public Health Social Work Consultant
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HEALTH CONSULTATION

PRELIMINARY HEALTH REVIEWS IN RANCHO CORDOVA, SACRAMENTO COUNTY, CALIFORNIA

AEROJET-GENERAL CORPORATION
RANCHO CORDOVA, SACRAMENTO COUNTY, CALIFORNIA
CERCLIS NO. CAD980358832
OCTOBER 16, 1997

Prepared By:

California Department of Health Services
Under Cooperative Agreement with the
Agency for Toxic Substances and Disease Registry

STATEMENT OF ISSUE

The Environmental Health Investigations Branch (EHIB), within the California Department of Health Services (CDHS), under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR), is conducting health assessment activities on the Aerojet-General Corporation (Aerojet) Superfund site in Sacramento County, California (See Figure 1). A Preliminary Health Assessment written in December 1988 recommended that when additional environmental information and data became available, ATSDR would make another assessment (1). A Site Review and Update written in March 1993 also recommended a health assessment be conducted when more data became available (2).

This health consultation is one in a series that will be performed as part of the ATSDR enhanced health assessment process at this site. During this process, data and information on the release of hazardous substances and their impact on public health will be evaluated. Five health consultations on perchlorate exposure in the drinking water supply have recently been written as part of this series (3-7). In this health consultation, we will focus on three preliminary reviews of health outcome data gathered on individuals living in areas potentially affected by the perchlorate-contaminated drinking water. These reviews focus on specific health outcomes related to biologically-plausible effects from exposure to perchlorate. These reviews include: data from the Genetic Disease Branch of CDHS pertaining to neonatal hypothyroidism, hospital discharge data from the Office of Statewide Health Planning and Development (OSHPD) of CDHS pertaining to goiter, agranulocytosis and aplastic anemia and information from the California Cancer Registry for childhood leukemia.

BACKGROUND

Aerojet began operation in the Rancho Cordova area of California in 1951. Since that time, Aerojet has manufactured liquid and solid propellants for military and commercial rocket systems and has fabricated, assembled, tested and rehabilitated rocket engines (1). In addition, between 1974 and 1979, Cordova Chemical Company, a wholly-owned subsidiary of Aerojet, manufactured paint components, herbicides, and pharmaceutical products within the facility boundaries. Over the years, Aerojet and Cordova Chemical disposed of hazardous waste by burial, open dumping, discharge into unlined ponds, and injection into deep underground wells (1). Monitoring demonstrated perchlorate in the groundwater, which was thought to have arisen from ammonium perchlorate, a main component of solid rocket fuel. In addition to the natural migration of perchlorate-contaminated groundwater from the site, Aerojet has been reinjecting water treated to remove trichloroethylene, but still contaminated with perchlorate, back into the groundwater at the site's western and northern boundary. Some of these discharges, including perchlorate, moved off-site of the Aerojet facility boundary (Figure 1) and contaminated several drinking water wells of the Arden Cordova Water District (7). The Regional Water Quality Control Board (RWQCB), the lead regulatory agency, is also investigating other potential sources of the perchlorate, such as the McDonnell Douglas or Purity Oil sites.

The Arden Cordova Water Service is composed of two distinct systems, the Arden System and the Cordova System (Figure 1). These systems are not interconnected (i.e., the wells located in the Cordova System serve only the Cordova System customers). The Cordova System has been impacted by the perchlorate contamination, whereas the Arden System is located several miles west of the contamination and thus it is unlikely that it will ever be affected (7). The Cordova System supplies water to 11,650 connections, approximately 36,500 customers, mostly family residences and commercial businesses (8). It is believed that perchlorate first contaminated wells in the Cordova System as early as 1987; however, it was not until February 1997 that the distribution of water from affected wells was stopped. Currently, drinking water wells 13, 15 and 16 remain closed (due to levels of 220, 95 and 210 parts per billion (ppb) perchlorate,

respectively). Additionally, three wells which initially were closed in April 1997 [wells 11 and 14 (4.4 ppb perchlorate each) and well 19 (6.8 ppb perchlorate)] have been reopened and are again serving customers, as of June 1997 (7). A prior health consultation concluded that a completed exposure pathway to perchlorate-contaminated drinking water for residents and employees served by the Arden Cordova Water District existed and that this water may have posed a health hazard to exposed individuals during the length of time that these wells were in use (7).

Currently, there remains much debate over the health effects related to perchlorate ingestion and considerable uncertainty pertaining to the levels of perchlorate which are believed to be of danger to the public health. At present, the U.S. Environmental Protection Agency (U.S. EPA) has a provisional oral reference dose (RfD) for perchlorate (0.0001-0.0005 mg/kg/day) which is an estimate of a daily exposure to the human population that is likely to be without appreciable risk of deleterious effects during one's lifetime (10). However, this level may be a more conservative estimate by a factor of 300 to 1000 due to toxicological uncertainties involved. Additionally, the detection limit for perchlorate in drinking water was just recently decreased by the availability of more advanced methods of testing, so that wells which were previously thought to be uncontaminated were more recently found to contain small amounts of perchlorate. These factors may have contributed to the appearance that people may have been receiving perchlorate-contaminated drinking water for almost ten years without any prior health agency response.

DISCUSSION

Preliminary reviews of the scientific literature were conducted by CDHS personnel located in the Environmental Health Investigations Branch looking for known health effects from exposure to perchlorate. Searches of the pertinent human and animal data bases found that the primary organ which is affected by perchlorate is the thyroid gland. However, there is a very small amount of information available related to perchlorate ingestion in healthy, human subjects; most of the information was found in studies of patients with Graves' Disease (hyperthyroidism), where perchlorate was used as an antagonist to decrease circulating thyroid hormone levels. Aside from producing hypothyroidism, perchlorate ingestion may also have produced goiter and hematologic abnormalities.

Several statewide databases were surveyed for these possible perchlorate-related health outcomes during the suspected years of contamination and limited to the likely areas of exposure (by zip code). Corresponding specific exposure information was not available at this time, so exposure was broadly defined as residing in a suspected contaminated zip code during the period from 1985 to 1996.

Neonatal Thyroid Hormone Levels

Little medical information is available on perchlorate's developmental toxicity; however, it is believed that perchlorate acts in a fashion similar to other anti-thyroid medications (propyl thiouracil and methimazole) by crossing the placenta and inhibiting fetal thyroid synthesis, thus producing hypothyroidism in the newborn (9). Neonatal hypothyroidism can have tragic health consequences including mental retardation and cretinism, but can be treated, if problems are ascertained early. In California, thyroid hormone levels (T4) are drawn and maintained on file with the Genetic Disease Branch of the CDHS for all newborn infants. In a preliminary survey, thyroid hormone levels were obtained for all children born to mothers believed to have been exposed to perchlorate by residing in the following zip codes: 95670, 95742, 95655 and 95827. Additionally, data were abstracted for those children born to mothers residing in neighboring areas not believed to have been exposed to perchlorate from zip codes 95628, 95608, 95864 and

95662, as well as data from the remainder of California. The time period for this abstracted information was from 1985 through 1996.

There were 11,814 thyroid hormone screens in the potentially-exposed area with 4 cases of hypothyroidism observed. 3.76 cases would have been expected based on the statewide rate of 3.18 cases per 10,000 live births during this period. The non-exposed area found 6 cases of hypothyroidism out of 20,135 routine blood screens (6.41 cases were expected). Table 1 shows these figures for exposed and unexposed zip codes as well as for the remainder of the state. These data do not show strong evidence of an association between residence in the potentially-exposed zip codes and neonatal hypothyroidism. Additionally, using residence as a proxy for exposure places limitations on the validity of any findings of this preliminary survey as there is no well-documented exposure information for the birth mothers. In addition, there are numerous other causes for neonatal hypothyroidism which instead may be responsible, including: deficiencies of Thyrotropin Releasing Factor and Thyroid Stimulating Hormone, aplasia or hypoplasia of the thyroid gland and iodine deficiency (9).

In addition to the above preliminary analysis, values of thyroid hormone (T4) and thyroid stimulating hormone (TSH) were obtained for each group, looking for differences in mean and median values between the exposure groups(Tables 2 and 3, respectively). It should be noted that TSH levels are not routinely obtained in the initial screen of all live births, but are ascertained secondarily from neonates with low initial T4 levels (below 10 Iu/dl) who are then re-screened.

The mean neonatal thyroid hormone value in the potentially-exposed zip codes was statistically significantly lower than the non-exposed population ($p=0.0001$), yet statistically significantly higher than the population from the rest of the state ($p=0.0001$). If neonatal thyroid hormone levels were affected by maternal perchlorate ingestion, then one would expect the group levels in the exposed population to be lower than both populations. In addition, since exposures were not more accurately determined through dose-reconstruction analyses, it is not possible to more accurately assess whether perchlorate was responsible for the levels of T4 observed in the exposed group. For TSH values, the mean level observed in the suspected exposed group was not statistically significantly different from either the unexposed group ($p=0.49$) or the values found throughout the rest of the state ($p=0.99$).

Finally, it was also noted that from 1985 through 1996 there were only four cases of clinically significant neonatal hypothyroidism in the suspected exposure zip code area (Table 1). One case was born in 1985 and the birth mother resided in zip code 95827. This case's mother may not have regularly ingested contaminated water as the zip code location is the furthest west from the Aerojet facility and the time period may be before the drinking water wells in the Arden Cordova service area were affected by perchlorate contamination. The other three cases occurred from 1990 through 1996 and were all located in zip code 95670, which is the approximate area where perchlorate contamination of the drinking water wells is located. However, further information was unavailable to better define exposure status, without interviewing the family or reviewing the child's medical record.

Goiter

Perchlorate competitively binds to receptors on the surface of the thyroid and limits the uptake of iodide by the thyroid gland, with the subsequent inhibition of thyroid hormone release. Decreased circulating thyroid hormone exerts a feedback effect on the pituitary gland producing a compensatory increase in TSH. TSH stimulates the thyroid gland and may produce hypertrophy and thyroid gland enlargement (10). The OSHPD hospital discharge data base was reviewed, searching for the diagnosis of goiter among the first five reported diagnoses for each hospitalized individual residing in zip code 95670 from 1991 through 1995[1]. [The information obtained in this and the remaining surveys searched only in the 95670 zip code because this area was viewed as the most likely area of possible perchlorate contamination of the drinking water supply.] There were approximately 3-5 cases per year of goiter listed in the top 5 diagnoses. There are however, several problems with this approach. First, there are many diseases or conditions which can produce a goiter other than perchlorate ingestion and the data base cannot differentiate this aspect well. Also, not all patients with goiter are admitted and treated in a hospital setting and so the OSHPD count is probably an undercount of the actual number of people with goiter. Because of these reasons, it was concluded that OSHPD data would not be helpful in determining the prevalence of thyroid enlargement in the affected water district.

Agranulocytosis/Aplastic Anemia

Aplastic anemia is a condition affecting the development of early blood cell precursors in the bone marrow which results in pancytopenia (reduced red and white blood cells and platelets). Agranulocytosis is the reduction of one particular blood cell line (white blood cells). Both aplastic anemia and agranulocytosis have occurred in individuals with Graves' Disease treated with perchlorate, documented in a series of papers in the early 1960s, which ultimately led to the discontinuation of perchlorate for the treatment of this condition (10). However, it is thought that the aplastic anemia seen in the Graves' Disease patients may have been a hypersensitivity reaction and unrelated to the dose of perchlorate ingested. Also, there is no information which would suggest that individuals without Graves' Disease would react in a similar fashion to perchlorate. Finally, aplastic anemia and agranulocytosis both may be caused by exposure to a variety of drugs or conditions including: cytotoxic medicines used in cancer chemotherapy, anticonvulsants, antibiotics, benzene, radiation, viral infections and genetic syndromes (11).

The OSHPD data was reviewed from 1991-95 for individuals residing in zip code 95670, searching for agranulocytosis or aplastic anemia as one of the top five diagnoses. This zip code was chosen because it was presumed to be the most likely area receiving possibly perchlorate-contaminated drinking water. Table 4 displays OSHPD data for hospitalizations for agranulocytosis for individuals residing in zip code 95670 during this time. There were 76 total cases diagnosed with agranulocytosis who resided in this zip code from 1991 through 1995 for a rate of 35.8 cases/100,000 individuals per year. This figure is less than the statewide rate of 41.6 hospitalizations per 100,000 individuals per year generated from OSHPD data during 1994 and 1995. Because the data does not suggest any increase in risk of agranulocytosis for individuals residing in the suspected perchlorate-exposed area and there are other more likely causes for agranulocytosis, a further search of this data was not conducted.

Table 5 lists the number of cases of aplastic anemia diagnosed in individuals who resided in the 95670 zip code from 1991 through 1995. For the five year time period, there were eight hospitalizations for 95670 zip code residents for a rate of 3.8 hospitalizations per 100,000 individuals per year, which is higher than the statewide rate of 2.2 hospitalizations per 100,000

[1] The OSHPD maintains a computerized data base of all discharges to California hospitals for each year. Pertinent patient information found in this data base includes: primary diagnosis with listings of additional diagnoses, demographics and treatments performed while hospitalized.

individuals per year. However, all but one of the eight hospitalizations also had an additional diagnosis of cancer or chemotherapy or radiation which would seem to be the likely explanation for aplastic anemia, as chemotherapeutic agents and radiation treatments have been shown to produce bone marrow aplasia. It was not felt that reviewing the medical records of these individuals would provide meaningful information on the possible role of perchlorate.

Childhood Leukemia

Leukemia is cancer of the white blood cell lines. Acute Lymphoblastic Leukemia (ALL) is the most common malignancy among children less than 15 years of age (12). Acute Myeloblastic Leukemia (AML) is the second most common childhood malignancy with about 400 new cases occurring annually in the United States (13). It has been postulated that risk factors for childhood leukemia include maternal exposures during pregnancy to radiation, infectious agents, pesticides, and genetic factors (12,13). No information concerning perchlorate's relationship with leukemia was found in the medical literature, however information concerning childhood leukemia was readily available in the Cancer Registry data base. The California Cancer Registry, Region 3, provided information on all childhood leukemia cases from their data files for individuals residing in zip code 95670 from 1987 through 1996.[2] During that time, there were four cases in children aged less than 14 years, consisting of three cases of ALL and one case of AML. Since the total child population of this zip code was 9,648 individuals by the 1990 Census, the crude rate of childhood leukemia was calculated to be 4.2 cases per 100,000 children per year [4 cases/(9,648 people X 10 years)]. This rate is less than the corresponding childhood leukemia rate for California from 1988 through 1992 of 4.68 cases per 100,000 children per year. Based on this information and the fact that additional factors may be responsible for childhood leukemia, it was not recommended that further study be performed reviewing childhood leukemia statistics at this time.

CONCLUSION

The preliminary information which was reviewed included: neonatal thyroid hormone levels, goiter, agranulocytosis, aplastic anemia and childhood leukemia in individuals residing in zip codes near Aerojet (which were used as a proxy for exposure to perchlorate) during the assumed time period that perchlorate contaminated the Arden Cordova drinking water system. Investigation found that:

- mean neonatal thyroid hormone levels were higher in the suspected exposed zip codes than the corresponding statewide rates (lower mean levels would have suggested a possible effect of perchlorate);
- there was no increase in cases of neonatal hypothyroidism in the exposed zip codes than expected;
- the OSHPD data base was not considered a useful source of information for assessing the incidence of goiter;
- there was no increase in the rate of hospitalizations for agranulocytosis;

[2] The CCR is the statewide population-based cancer surveillance system which gathers information on all cancers diagnosed in California since 1988 (excluding basal and squamous cell carcinomas of the skin and carcinoma in situ of the cervix). Hospitals and physicians are required by law to refer information to the CCR's network of ten regional registries which perform analyses and conduct studies on this data.

- cases of aplastic anemia in a suspected perchlorate-exposed zip code was higher than the statewide rate, but most of the cases in the affected area were related to other likely causes, such as chemotherapy, radiation or AIDS infection;

- childhood leukemia rates were not elevated in an affected zip code compared to the statewide rate.

The major handicap with these preliminary studies was the limitation imposed by the lack of good exposure measurements in the affected population. It is unclear at this time exactly when the perchlorate groundwater plume first contaminated the drinking water supply of the Arden Cordova System. Thus, the time periods analyzed may have been too broad. The other difficulty with using zip codes as proxies for exposure is that there are more refined dose-reconstruction techniques used in hydrological modeling, which may better determine which neighborhoods or streets received contaminated water. Here again, one must assume that zip codes are much less reflective of actual exposure to perchlorate-contaminated drinking water and that the actual number of exposed persons may be much smaller. Finally, the other difficulty with assessing these health outcome surveys is that perchlorate is not specific for producing thyroid dysfunction or hematological abnormalities. Thus, any case that was ascertained may have other, more likely causes.

Public Health Recommendations and Actions

The Public Health Recommendations and Action Plan (PHRAP) for this site contains a description of actions taken, to be taken, or under consideration by ATSDR and CDHS at and near the site. The purpose of the PHRAP is to ensure that this health consultation not only identifies public health hazards, but also provides a plan of action designed to mitigate and prevent adverse human health effects resulting from exposure to hazardous substances in the environment. The CDHS and ATSDR will follow-up on this plan to ensure that actions are carried out.

Actions Completed

1. CDHS performed preliminary surveys of health outcomes related to known or suspected effects of perchlorate ingestion by individuals in zip codes nearby to the site.

2. CDHS prepared a fact sheet about perchlorate and health. CDHS made this fact sheet available to the affected water purveyors, including the Arden Cordova Water Service to provide to their customers.

Actions Planned

1. The Air Force and the Perchlorate Work Group are sponsoring an investigation into fate and transport questions regarding perchlorate. They will investigate the skin permeability of perchlorate.

2. The Air Force and the Perchlorate Work Group are sponsoring a series of animal investigations to address some of the information lacking in perchlorate toxicology. Several animal toxicology studies will be funded to review the genetic and neurological toxicity of perchlorate.

3. CDHS is investigating the feasibility of conducting an exposure investigation and will model perchlorate contamination of the Arden Cordova drinking water supply.

4. ATSDR and CDHS are investigating the feasibility of conducting an epidemiological investigation which would review the association between exposure to perchlorate-contaminated drinking water and neonatal thyroid levels.

Recommendations for Further Action

1. CDHS and ATSDR will continue communicating with the Arden Cordova Water System customers about the perchlorate issue.

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Appendix

Table 1: Neonatal hypothyroidism status for potentially-exposed and unexposed zip codes in California, 1985-1996.

Exposure Status/Location	Hypothyroid Cases (expected cases)	Total Screens
Rancho Cordova (exposed)	4 (3.76)	11,814
Rancho Cordova (unexposed)	6 (6.41)	20,135
Rest of State (unexposed)	2,068 (-)	6,494,193

Table 2: Neonatal thyroid hormone values (T4) per suspected exposure group, 1985-1996.

Exposure Status	Number of Screens	Mean	Median	Standard Deviation
Exposed	11,773	15.04	14.6	4.57
Unexposed	20,077	15.27	14.9	4.57
Rest of State	6,479,190	14.77	14.4	4.38

Table 3: Neonatal thyroid stimulating hormone values (TSH) per suspected exposure group, 1985-1996*.

Exposure Status	Number of Screens	Mean	Median	Standard Deviation
Exposed	1368	8.6	5	20.9
Unexposed	2105	8.99	6	21.1
Rest of State	799820	8.59	6	17.3

* TSH values are not routinely obtained on every newborn child, but are determined from a second phase of testing on those neonates with borderline-low initial levels of thyroid hormone.

Table 4: Hospitalizations listing agranulocytosis as one of the top five diagnoses for individuals residing in 95670 zip code, 1991-1995.

Year Diagnosed	Number of Cases	Rate/100K individuals*
1991	15	35.3
1992	20	47.1
1993	13	30.6
1994	10	23.6
1995	18	42.4
Total	76	35.8

* Rate = number of cases per year / 1990 census population of 42,457 x 100,000.

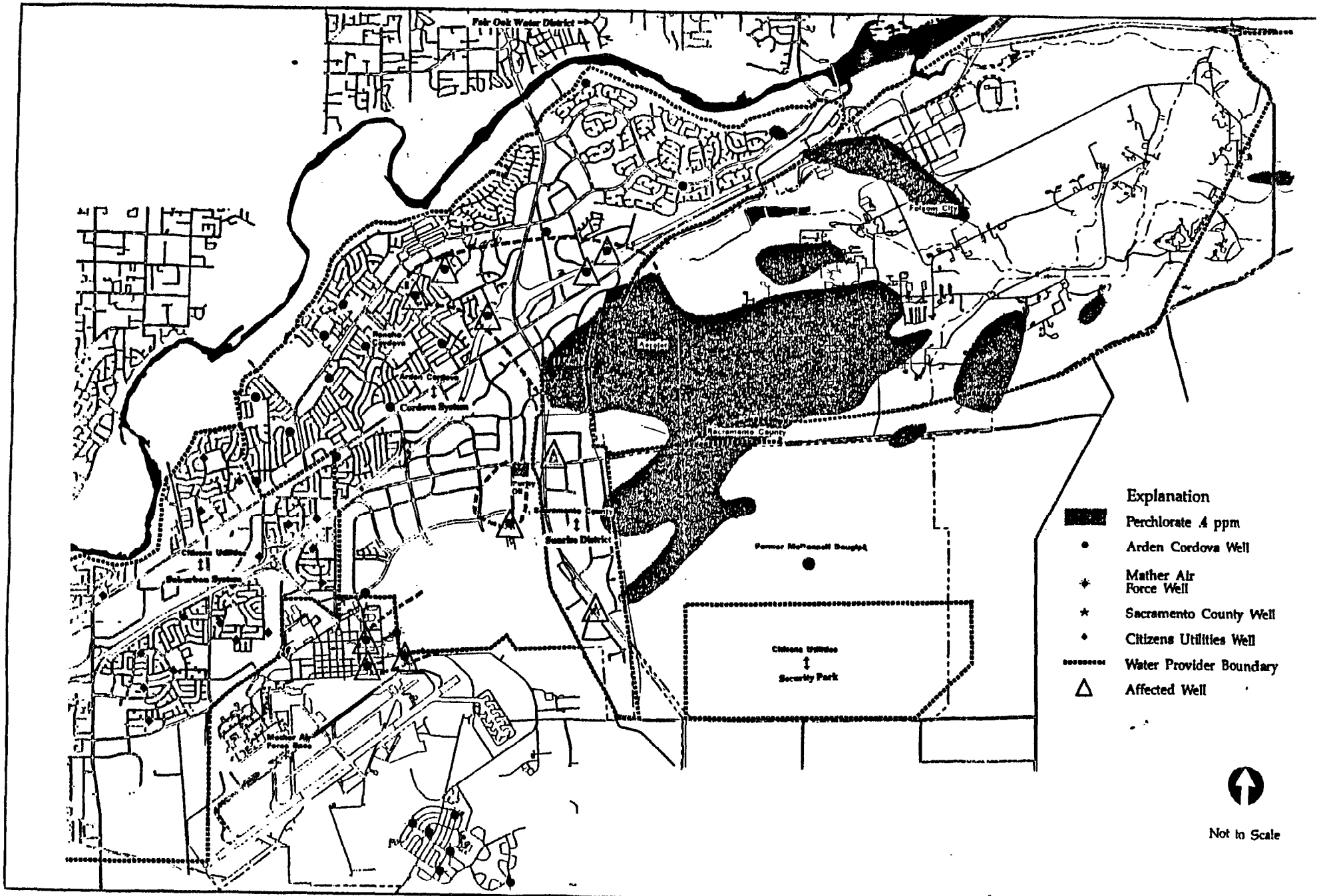
Table 5: Hospitalizations listing aplastic anemia as one of the top five diagnoses for individuals residing in 95670 zip code, 1991-1995.

Year Diagnosed	Number of Cases	Rate/100K individuals*
1991	4	9.4
1992	3	7.1
1993	0	0
1994	0	0
1995	1	2.4
Total	8	3.8

* Rate = number of cases per year / 1990 census population of 42,457 x 100,000.

Figure 1

Perchlorate Groundwater Plume in Relation to Aerojet and the Citizens Utilities Suburban System



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CERTIFICATION

This Aerojet-General Corporation Health Consultation was prepared by the California Department of Health Services under a cooperative agreement with the Agency for Toxic Substances and Disease Registry (ATSDR). It is in accordance with approved methodology and procedures existing at the time the health consultation was begun.

Richard R. Kauffman, M.S.
Technical Project Officer
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The Division of Health Assessment and Consultation, ATSDR, has reviewed this health consultation and concurs with its findings.

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